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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/211,691 12/14/98 GILBERT

M 14137-129-10

020350 HM22/1109  
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EXAMINER

TUNG, P

ART UNIT

PAPER NUMBER

1652

DATE MAILED:

*H*  
11/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.  
**09/211,691**

Applicant(s)  
**Gilbert et al.**

Examiner  
**First Last**

Art Unit  
**1234**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Aug 27, 2001
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above, claim(s) 28-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 and 33-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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## **DETAILED ACTION**

### ***Continued Prosecution Application***

1. The request filed on 8/27/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/211,691 is acceptable and a CPA has been established. An action on the CPA follows.

### ***Election/Restriction***

2. Claims 1-35 are pending. Claims 28-32 are withdrawn from further consideration as being drawn to a non-elected invention.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-27 and 33-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a

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disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The breadth of the claims encompass a polynucleotide encoding a catalytic domain of a glycosyltransferase and a catalytic domain of an accessory enzyme which catalyzes a step in the formation of a nucleotide sugar. However, insufficient examples and guidance are provided on catalytic domains of any glycosyltransferase or said accessory enzymes. The skill of those in the art is low in determining the catalytic domains of an enzyme and the prior art does not teach catalytic domains of a glycosyltransferase or said accessory enzymes. Additionally, by only having the catalytic domains of said enzymes, one of skill in the art would not necessarily know how to use the fusion protein as a protein comprising only the catalytic domain would not necessarily have enzymatic function. Undue experimentation would be required to make and use the invention based upon the instant disclosure.

5. Claims 1-27 and 33-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide which encodes a fusion protein comprising a specifically identified glycosyltransferase and a specifically identified accessory enzyme, does not reasonably provide enablement for a polynucleotide which encodes a fusion protein comprising any glycosyltransferase and any accessory enzyme which catalyzes a step in the formation of a nucleotide sugar which is a saccharide donor for a glycosyltransferase. The specification does not

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enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The breadth of the claims encompass a polynucleotide encoding a fusion polypeptide comprising a catalytic domain of any glycosyltransferase and a catalytic domain of any accessory enzyme which catalyzes a step in the formation of a nucleotide sugar which is a saccharide donor for said glycosyltransferase. Insufficient guidance and working examples are provided of polynucleotides encoding a fusion enzyme comprising a glycosyltransferase and the specific accessory enzyme. One of skill in the art would not know how to make or use a polynucleotides encoding a fusion enzyme comprising any glycosyltransferase with any accessory enzyme. Without a specific accessory enzyme, one of skill in the art would not know how to make and use the glycosyltransferase. Without a specific glycosyltransferase enzyme, one of skill in the art would not know how to make and use the appropriate accessory enzyme. Additionally, the breadth of the claim of an accessory enzyme which catalyzes a step in the formation of a nucleotide sugar encompasses any enzyme involved in any step of biosynthesis of a nucleotide or a sugar. Insufficient guidance and examples are

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provided on those enzymes which are encompassed by said accessory enzymes. Undue experimentation would be required to enable the full scope of the claims based upon the instant disclosure.

6. Claims 1-14, 16-27 and 33-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Adequate description for the species encompassed by the claim would have relevant identifying characteristics which include 1) structure, 2) physical and/or chemical characteristics, 3) functional characteristics when coupled with a known or disclosed correlation between function and structure, 4) a combination of these. The instant claims are drawn to DNA encoding a glycosyltransferase and an accessory enzyme which catalyzes a step in the formation of a nucleotide sugar. However, no DNA sequences or sufficient methods to obtain those DNA sequences are provided. No correlation is disclosed or is well known relating functional characteristics with structure. Therefore the claimed DNAs are inadequately described.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 4, 9, 33 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 4 is indefinite as it is unclear how a catalytic domain of a glycosyltransferase would have included domains or regions which were not involved in catalysis, i.e. cytoplasmic domain, signal-anchor domain and stem region.

10. Claim 9 is unclear as to the members of the Markush group. It is not clear if the GDP mannose enzymes are grouped as one cluster of accessory enzymes or if they are to be considered each as separate members of the Markush group.

11. Claims 33 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: and isolating the fusion polypeptide.

### *Conclusion*

12. All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing under 37 CFR 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Tung, Ph.D. whose telephone number is (703) 308-9436. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D., can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



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